



YENEPOYA

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

YENEPOYA (DEEMED TO BE UNIVERSITY)


Deralakatte, Mangaluru -575018

REGULATIONS AND CURRICULUM GOVERNING

POSTGRADUATE PROGRAM

M.Sc. IN RESEARCH ETHICS

(REVISED CURRICULUM – AMENDED UPTO 2020)

ATTESTED

Dr. Gangadhara Somayaji K S
Registrar
YenePOYA (Deemed to be University)
University Road, Deralakatte
Mangalore 575 011



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Office of the Registrar
University Road
Deralakatte, Mangalore – 575 018
Ph: 0824 – 2204667/68/69/70/71
Fax: 0824 - 2203943

NOTIFICATION – 38-ACM/2020 dtd. 14.05.2020

Sub: Proposal for amendments in evaluation process for M.Sc.
Research Ethics

Ref: Resolution of the Academic council at its 38th meeting held on
27.04.2020, vide agenda -5

The Academic Council at its 38th meeting held on 27.04.2020 and subsequently the Board of Management at its 49th meeting held on 30.04.2020 have resolved to accept the proposal for making amendments in the evaluation process for M.Sc. Research Ethics.

REGISTRAR

Copy to:

1. Controller of Examinations
2. Director, Centre for Ethics
3. Professor & HoD, Department of Forensic Medicine
4. File copy



YENEPOYA UNIVERSITY – FOGARTY INTERNATIONAL CENTER RESEARCH ETHICS MASTERS' PROGRAM FOR INDIA

- **Title:** Master of Science in Research Ethics (MSc Research Ethics)
- **Faculty:** Faculty of Medicine, Yenepoya University

Goals:

The goal is-

1. To start the first Research ethics masters program in India, so as to cater to the developing research, technology and innovation
2. To inculcate research integrity at micro and macro level.

Objectives:

The objectives of this program are

1. To build on the existing suite of teaching programs and activities of the Centre for Ethics at Yenepoya University by offering a Master's in Research Ethics
 2. To ensure that the Master's curriculum is comprehensive, incorporating knowledge of ethical principles, processes, and policies related to local and international, clinical and public health research, including Indian systems of medicine (includes Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy, acronymized to AYUSH)
 3. To ensure that the curriculum enhances practical skills in research methods, ethics education, ethical review, transformational leadership, and consultation
 4. To encourage and maintain the involvement in teaching, of national and international experts in bioethics and research ethics, so students are exposed to a broad range of views and approaches
 5. To facilitate transfer of skills in research ethics and create a national pool of leaders
 6. To support and mentor students who wish to perform roles in ethics-related teaching, research and practice, and in publishing their work
 7. To inculcate responsible research conduct in the students
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8. To expand the suite of activities available to alumni
9. To strengthen ethical research environs in India, by increasing ethics-trained researcher pool

- **Minimum Eligibility:**

Bachelor's degree in any science field (*preferably from a healthcare background*) from a UGC recognized college/university or its equivalent.

Curriculum Blueprint

S No	Module	Specific Learning Objectives	Content
SEMESTER ONE			
Week 1	Introduction	Icebreaking and group forming Orientation Mentoring Journals -Describing course objectives and overview - Know the origins of modern bioethics - Locate the importance of bioethics in the backdrop of the history of research	Introduction to modern bioethics Historical development of bioethics

Weeks 2/3	Moral reasoning and ethical theory	Describe the ethical theories Know what is moral reasoning and how it influences our choices	Utilitarianism Deontology Virtue theory Care ethics Justice theory Moral reasoning using Milgram experiment, Stanford prison experiment and others
Weeks 4/5/6	Biomedical ethics	Know what is respect for person Understand the philosophical underpinnings of respect of person Describe the process of informed consent Know the various types of informed consent Know what is beneficence	Ethics principles: Dignity and respect for person Informed consent Beneficence Non-maleficence Justice (including ethics of HIV and Ebola –

		Know what is non-maleficence Know what is justice and its various types	stigma/discrimination) Criticism of the four principles approach
Week 7	Moral Theories – Indian perspectives	Know about different schools of moral philosophy in Indian culture Understand approaches to ethical issues in systems of Indian medicine Understand similarities and differences in theory and practice of health care ethics between Indian and Western approaches	Hindu, Islamic, Buddhist and other Indian moral approaches with a focus on ethical issues in health, medical practice and research

Week 8	Historical aspects of Research ethics	Background and key debates	World War 2 Nazi and Japanese experiments Nuremburg Code, Tuskegee, Henry Beecher, Maurice Papworth, Belmont, Guatemala Tropical Medicine, 10/90 split International health research
Weeks 9/10	Introduction to research methods	Know about collection analysis of qualitative and quantitative data Choose appropriate methods for specific research studies Skills to collect and analyze qualitative and quantitative data Identify key issues in research	Overview of basic epidemiology, biostatistics, qualitative and quantitative methods, research design and research methodology
Weeks 11/12	Critical appraisal	Able to identify specific research objectives, study design and methods used in the study under review Able to assess the fitness of the study design and methods Able to interpret findings presented in the study Able to critically evaluate the discussions and conclusions of the study	Appraisal methods for different types of research (with use of itemized checklist, systematic review checklist) Parametric and non- parametric tests
Weeks 13/14	Human Rights, Public Health, and Medical	Know the process of policy making Understand how	International and local
	Law	legislation, regulation and advocacy influence public health policies Identify moral and ethical problems in public health research	law as it applies to health and health research, public health policies

Week 15	International guidelines and laws relating to research	Be cognizant with the international laws, regulations and guidelines relevant to research	Food & Drug Act Nuremberg Code International code of medical ethics Declaration of Helsinki 45 CFR 46 including subparts B and C (pregnant women and prisoners) Belmont report, CIOMS WHO guidelines for ethics committees
SECOND SEMESTER			
Week 1:	Synopsis completion week	To complete the synopsis and submit to University as per university timeline	Adding finer details and finishing touches and completing final check list for the completion of the synopsis
Week 2:	Ethics of Indian systems of medicine Clinical trial designs	Know the different Indian systems of medicine prevalent in India Know the regulations that govern the practice of these systems Describe ethical issues in research in these systems of medicine Be familiar with the commonly used clinical trial designs	Introduction to AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy) Concept of positive health and wellness Regulations and laws regarding practice and research of AYUSH Ethical issues thereof Phases of CTs Randomization FIH studies
Week 3:	Ethics of storage of body parts, tissues and biobanks	Describe the utility of biobanks Know when to use stored samples Identify and address the ethical issues in storage, retrieval and usage of stored tissues	Models of biobanks, functioning of biobanks, ethical and legal issues of stored tissues Global and local variations, data safety, privacy and confidentiality
Week 4:	Responsible Conduct of Research – 2	Know importance of maintaining good records and data	Undertaking the practice of scientific research with integrity

		<p>Know how to handle data and data sharing</p> <p>Define conflict of interest (CoI)</p> <p>Know how to avoid CoI</p> <p>Define medical errors & negligence,</p> <p>Error reporting</p> <p>Describe the various aspects of research misconduct</p> <p>Define plagiarism (revision)</p> <p>Describe the various authorship issues (revision)</p>	<p>with special attention handling misconduct, conflict of interest, collaborative research, research misconduct and handling, publication ethics</p>
<p>Weeks 5/6/7:</p>	<p>Research Ethics – Indian laws & regulations</p> <p>Week 5: Schedule Y (Drugs & Cosmetics Act)</p> <p>Week 6: ICMR guidelines - 1</p> <p>Week 7: ICMR guidelines – 2</p>	<p>Understand the importance of adhering to ethical principles in health care research</p> <p>Know the key issues in health care research</p> <p>Familiarize with the laws and guidelines relating to research ethics (Drugs and cosmetics act; Indian Council of Medical Research ethical guidelines;</p>	<p>Drugs and Cosmetics Act with amendments (focusing on Schedule Y)</p> <p>ICMR guidelines 1 (Risk-benefit assessment; Informed consent process; privacy/ confidentiality)</p> <p>ICMR guidelines 2 (compensation; post-trial access; conflict of interest; vulnerability)</p>
<p>Week 8:</p>	<p>Disaster research ethics</p> <p>Health Technology Assessment</p>	<p>Differentiate types of disasters</p> <p>Classify disasters</p> <p>Describe methods of mitigation</p> <p>Assess gaps in disaster research and the ethical issues thereof</p> <p>Be familiar with the process of health technology assessment for new devices, implants, diagnostic procedures</p>	<p>Ethical issues in disaster, and research in disaster</p> <p>Impact of disasters on children and female population</p> <p>Development of guidelines</p> <p>Health Technology Assessment</p>

Week 9:	Environment Ethics	<p>Know the interrelatedness of ecosystems</p> <p>Describe the theories related to environmental ethics</p> <p>Describe the ethical challenges in environment-related research</p>	<p>Integrity, accountability, conflict resolution, communication skills, leadership, responsible global citizenship</p>
Week 10:	Genetic technology	<p>Know the basics of molecular biology, recombinant DNA and human genetics</p>	<p>Ethics of genetic technology, the background, use in therapy and enhancements.</p>
		<p>Identify and address the ethical issues in body enhancements</p>	<p>Introduction to somatic and germ cell therapy</p> <p>Status of research in stem cell therapy</p>
Week 11:	<p>Animal Ethics</p> <p>Mid-semester revision</p>	<p>Be familiar with the laws and guidelines relating to the use of animals in research</p> <p>Revise all the topics covered so far</p> <p>Downtime to complete assignments</p>	<p>Committee for the purpose of control and supervision of experiments on animals (CPCSEA) guidelines</p>
Week 12:	<p>Communities and Vulnerability Practicum</p>	<p>Determine criteria for participation in health care research by vulnerable populations</p> <p>Understand sensitivity to priorities and needs by vulnerable population</p> <p>Skills to facilitate informed consent of vulnerable participants in health care research</p> <p>Know about and develop skills related to participatory research</p>	<p>Field visits and placements</p> <p>On-site lectures</p>
Week 13	Public Health Ethics	<p>Know the applications of ethics in the field of public health implementation and policy</p>	<p>Ethical issues in specific public health situations (vaccine trials, vaccine policies, research in public health)</p>

Weeks 14-15:	Research Unit 2	Extensive library search and compilation of review of literature Refining of the objectives	Developing questionnaire or other relevant tool Validating and pilot testing of the tool (as and when necessary)
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SEMESTER THREE

week 1		-	Preparation for exam
week 2		-	Revision class
week 3	Application of research ethics in social science research	History of social sciences, philosophy of social sciences, research ethics controversies and	Evolution of guidelines and governance mechanism in social sciences research
week 4	Applied research ethics in HIV medicine	Ethical issues in HIV research, Indian context	

week 5	Quantitative research basics	Introduction to research methods in health and allied themes, Research designs and methods	Literature Review Methods, Mixed Methods approach, Qualitative research methodologies
week 6	Practicing Ethics in Research and Innovation	Practicing ethics in research and innovation, Technology assessment & health technology assessment, Anticipatory technology ethics, Value sensitive design, Paternalism, Justice Theory	The ethical matrix, Ethics canvas, Nanomedicine, Nudging, Artificial intelligence
week 7	Roles and responsibilities of ethics committee		

week 8	Medicolegal aspects and public Health	Human rights AI	Human rights and Ebola virus outbreak. AI, Brain computer interphases Ethics of Deep Brain Stimulation Studies, Ethical issues of Biometric registration
week 9	Community based research ethics	Overview of Public Health, Reflections on Success Stories of Public Health Interventions, Advocacy, Legislation & Public Health,	Community Engagement, Community Based Participatory Research, National Health Policy and Sustainable development goals
week 10	Research progress review and presentation	-	
week 11	Application of research ethics in policy-making	Review of Public Health Research, Status of primary health care in India, Epidemiology and research, Health policy and systems research, Implementation research, Research on big data	Understanding the application of research ethics in policy making in various contexts including big data, epidemiology, healthcare
week 12	Implementing informed consent in research	Research Involving Children and Adolescents, Ethical Issues in CHIM (Human Informed Consent, Cluster Randomized Trials and Implementation Research, Deception in Social and Behavioral Research	Informed consent Assent Electronic consent
week	EC scope. Mandate	Ethical review process	Understanding the process in

13/14/15/16	and SOP construction	Post approval processes-1 Post approval processes-2	ethical review, approval and post-approval monitoring
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SEMESTER FOUR

Weeks 1-16	Project work	Data collection Analysis Statistical tests Report writing s	Submission to the Centre for Ethics
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- **Teaching learning modalities including online instruction/contact program:**

- a. Classroom teaching (active lectures)
- b. Library assignments
- c. Online assignments
- d. Skits, role plays, reflective essays, collage, poetry writing
- e. Practicum
- f. Research/capstone project: A short research performed and submitted in publishable format.

- **Evaluation**

- a. Internal: Regular continuous assessment will be done by the faculty and assessed by the program director. *Since the program aims at producing attitudinal change in the participants the examination will be designed innovatively. The continuous assessment will involve reflective essays, critical appraisals of audio-visual documentaries and case-study analysis.*
- b. University exams: Annual examinations (theory and practical) will be held each year. One External from the panel of external examiner and one internal examiner conduct the exams.

The evaluation of project defense of the M.Sc Research Ethics students by International faculty (external examiner) will be held through Skype portal (As per the amendment in 38 Academic Council Meeting).

c. Eligibility to appear:

1. 75% attendance (theory and practical separately)
2. Submission of assignments on time
3. Submission of research/capstone project on time
4. Internal assessment marks of at least 35% aggregate over the year.
5. Other eligibility criteria as per University rules.

d. Criteria for pass/first class/distinction:

1. Pass: a minimum of 50% in theory and practical separately
2. First class: 61-74% in theory and practical
3. Distinction: 75 % and above in theory and practical

- **Attendance requirements:** This is a full time program and attendance will be taken regularly as per the University rules. A minimum of 75% attendance in theory and practical separately will be acceptable for examination eligibility.